

## REMARKS

### **35 U.S.C. § 103(a) Rejections of Claims 1 – 20**

The Examiner rejected Claims 1 – 9 and 16 – 20 under 35 U.S.C. § 103(a) as being obvious over US 6,027,741 (US '741) in view of US 6,579,978 (US '978) and US 4,851,521 (US '521). Applicants respectfully disagree with the Examiner's contentions and traverse these rejections.

In the Final Rejection mailed July 15, 2009, the Examiner noted that US '741 teaches a sulphated HA coated on a biomedical object or device and that US '978 teaches that such a biomedical object may include cardiovascular stents. The Examiner added that US '521 teaches nonsulphated HA. The Examiner then argued that it would have been obvious to one having ordinary skill in the art to substitute the nonsulphated HA allegedly disclosed in US '521 with the sulphated HA of US '741 and US '978. Indeed, the Examiner stated that “[o]ne of ordinary skill in the art would have been motivated to substitute two equivalents, in this case HA ester derivatives, whether sulfated or non-sulfated, which are taught by the prior art to be useful for the same purpose.”

Sulphated HA and nonsulphated HA are not equivalents. Sulphated HA is much more soluble than nonsulphated HA. When coated on a biomedical object, such as a cardiovascular stent, sulphated HA dissolves much more rapidly than nonsulphated HA. Such a rapid dissolution rate diminishes the therapeutic benefits of such a coating. Indeed, to prolong the anti-thrombotic activity of sulphated HA, it is necessary to associate such compound with a natural, semi-synthetic or synthetic polymer. By contrast, nonsulphated HA, by itself, dissolves slowly, allowing for a controlled release and prolonged therapeutic benefits.

In view of these differences, it would not have been obvious to one having ordinary skill in the art to substitute nonsulphated HA for sulphated HA, and Applicant respectfully states that such a substitution by the Examiner is an improper use of hindsight. Indeed, US '741 and US '978 teach away from using nonsulphated HA, both specifically calling for sulphated HA. Further, while the Examiner noted that US '521 discloses that “HA may be used as an additive for a wide variety of polymeric materials for use in medical and surgical articles,” US '521 does not appear to disclose the use of any HA as a coating.

Applicant also argues that the Examiner's proposed combination does not include all of the limitations of Applicant's Claim 1. For example, the Examiner stated that US '521 discloses "non-sulphated esters of hyaluronic acid..." The Examiner, however, provides no support for her statement that US '521 discloses nonsulphated HA.

In an attempt to progress prosecution and without conceding the patentability of Applicant's previously presented claims, Applicants have amended Claim 1 to include all of the limitations of dependent Claims 2 and 4. Dependent Claims 2 and 4 have correspondingly been canceled.

Applicant respectfully requests that, in view of the foregoing, the Examiner allow Claims 1, 3, 5 – 9, and 16 – 20. Claims 10 – 15 are patentable for at least the same reasons, and Applicant respectfully requests that the Examiner allow these claims.

#### **35 U.S.C. § 103(a) Rejections of Claims 21 – 32**

The Examiner also rejected Claim 21 (and Claims 22 – 32, which depend on Claim 21) under 35 U.S.C. § 103(a) as being obvious over US '741 in view of US '978, US '521, and US 2002/082679 (US '679) and further in view of US 6,129,956 (US '956). Applicants respectfully disagree with the Examiner's conclusions and traverse these rejections.

The Examiner states that US '956 teaches "an object coated with polymeric material (polystyrene) and HA polymer coating" and adds that US' 679 teaches "polymeric material on a stent containing therapeutic agents." With these references, the Examiner argues that it would have been obvious to develop a stent comprising a second coating of a polymer with hydrophobic properties.

The structure of the layers described in US '956, however, is distinct from Applicant's invention. In US '956, a thin layer of HA is linked stably to an underlying material. *See, e.g.*, US '956, Col. 5, Ll. 6-23. In other words, this layer cannot be released; it is bound to the underlying material by chemical reaction. Thus, in Example 11 of US '956, to which example the Examiner cited, the thin layer of HA would be bound to and could not be released from the polystyrene (i.e., the hydrophobic polymer). By contrast, in Applicant's invention, the layer of nonsulphated HA releases slowly over time; it is not permanently bound to the hydrophobic polymer.

Applicant further notes that the layer of HA in US '956 would be unsuitable as a drug

reservoir because of its thinness, and therefore it would not be possible to associate this layer with a pharmacologically active ingredient. By contrast, in Applicant's invention, the layer of HA is thicker and thus can be associated with a pharmacologically active ingredient. *See, e.g.*, Claim 8.

For at least the foregoing reasons, as well as the reasons set forth above regarding Claim 1, Claims 21 – 32 are patentable, and Applicant respectfully requests that the Examiner allow these claims.

**Rejoinder**

Applicant believes Claims 1 – 32 are now in condition for allowance, and respectfully requests that currently withdrawn Claims 33 – 42 be rejoined, examined on their merits, and allowed.

**CONCLUSION**

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, arguments in support of the patentability of the pending claim set are presented above. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections are specifically requested and it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

No additional fees are believed due; however, the Commissioner is authorized to charge any fees due in connection with the filing of this response to our Deposit Account No. 50-1349. If a fee is required for an extension of time under 37 C.F.R. § 1.136 that is not accounted for in the enclosed transmittal, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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